

## EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6  
Full Quality Assurance System  
In Vitro Diagnostic Medical Devices

Registration No.: HL 60150609 0001

Report No.: 50334778 002

**Manufacturer:** Tianjin MNCHIP Technologies  
Co., Ltd.  
2102,2202, Building 2  
No.19 Xinhuan Rd. West, TEDA  
300457 Tianjin  
P.R. China

**Products:** (See attachment for Products included)

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2021-06-11

**Date:** 2021-06-11

Notified Body

Jing Zhang



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

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**Products:**

**In vitro Medical Devices for Self-testing:**

- Chemistry Analyzer & Electrolyte Panel Lyophilized Kits
- Liver Function Panel Lyophilized Kits
- Liver and Renal Function Lyophilized Kits
- Clinical Emergency Lyophilized Kits
- Renal Function Panel Lyophilized Kits
- Glucose and Lipid Panel Lyophilized Kits
- Myocardial Enzyme Panel Lyophilized Kits
- General Chemistry I Lyophilized Kits
- General Chemistry II Lyophilized Kits
- General Chemistry III Lyophilized Kits
- General Chemistry IV Lyophilized Kits
- Glucose & Lipid & HCY Panel Lyophilized Kits for Self-testing

**Date: 2021-06-11**

**Notified Body**

**Jing Zhang**

